

Serial No.: 10/620,404
Applicant: James M. Ntambi
Date of Office Action: 18 June 2010
Date of Response: December 17, 2010

REMARKS

In a non-final Office Action dated June 18, 2010, the Examiner in charge of the application incorrectly stated the status of the claims; Claim 6 and 8-11 are withdrawn from consideration, Claims 1-5 and 12-13 are cancelled, and Claim 7 is pending and under consideration. The Examiner withdrew her provisional rejection for alleged obviousness-type double patenting and rejection for alleged obviousness, but raised a new obviousness rejection, discussed below.

Rejection under 35 U.S.C. § 103

Claim 7 is rejected for alleged obviousness over Crooke *et al.* in view of Hayden *et al.* in further view of Ntambi (1999). The Examiner relied on Crooke's Claim 10 as teaching methods of inhibiting human stearoyl-CoA desaturase expression with an SCD antisense oligonucleotide. Further, Crooke teaches that stearoyl-CoA desaturase affects the ratio of stearate to oleate and that alterations to this ratio have been implicated in various diseases, such as non-insulin-dependent diabetes (Crooke, column 2, lines 1-5). Further, Crooke teaches that modulating nucleic acid function can result in either increased or decreased expression of a gene. Hayden's Claim 48 is directed at a method for treating diabetes and insulin resistance by administering to that individual an inhibitor of an SCD1 protein expression or activity. Ntambi teaches that membrane-bound SCD affects membrane fluidity and that alterations in the ratio of saturated and unsaturated fatty acids has been implicated in various diseases such as diabetes.

A combination of Crooke, Hayden, and Ntambi would not have made the invention obvious to the skilled artisan because the combination fails to teach or suggest the claimed method steps. Crooke merely as a matter of background teaches that SCD affects the stearate-oleate ratio and altered ratios are associated with certain diseases. From that, the Examiner alleged that it would have been obvious to one of skill in the art to observe an increase in insulin sensitivity following a reduction in SCD1 activity after administering an antisense oligonucleotide for SCD1 to a subject, as claimed. However, Crooke fails to teach or suggest any causal relation between decreasing SCD1 activity by administering antisense to a subject and increasing insulin sensitivity in the subject. The Examiner used impermissible hindsight to allege that a skilled artisan would have recognized a causal relation between SCD1 and diabetes,

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relying merely upon circumstantial evidence that SCD1 affects stearate-oleate ratio, a diabetes-associated physiological parameter.

Importantly, Crooke fails to teach or suggest one recited method step altogether, i.e., the step of measuring insulin sensitivity, as the Examiner acknowledged. This step of measuring insulin sensitivity was not obvious from the cited documents because prior to Applicants' work no link had been established between SCD1 and diabetes, much less between SCD1 and insulin sensitivity. Even if SCD1 was known to affect diabetes, it would not have been obvious that its down-regulation would increase insulin sensitivity.

The Examiner relied on Hayden and Natambi as allegedly teaching or suggesting the step of measuring increased insulin sensitivity. None of these documents teaches or suggests this step. Hayden's Claim 48, relied upon by the Examiner, is based on work by Applicants, named as inventors on the Hayden application. As such, Hayden is not available as prior art under section 102(e) and, consequently, is not available for a rejection under section 103. *See MPEP § 2136.05.* ("The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art." *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 15 USPQ2d 1816 (Fed. Cir. 1988). The issue turns on what the evidence of record shows as to who invented the subject matter. *In re Whittle*, 454 F.2d 1193, 1195, 172 USPQ 535, 537 (CCPA 1972)," emphasis original). Applicants submit herewith a declaration under 37 C.F.R. § 1.132 stating that Applicants invented the subject matter prior to the application for patent by Hayden. *See MPEP § 2136.05* (A "showing [of conception by the applicant before the filing date of the reference] can be made by submission of an affidavit by the inventor under 37 C.F.R. 1.132.").

Even if Hayden is available, Hayden does not teach or suggest the step of measuring increased insulin sensitivity. Likewise, Ntambi merely teaches that SCD activity is regulated by diet and insulin and that SCD activity was decreased in rats that are starving or afflicted with diabetes but increased in type II diabetes. Ntambi does not teach the step of measuring insulin sensitivity after administering an antisense molecule to a subject. The Examiner also failed to demonstrate any motivation to combine the cited documents. Even if one would have been motivated to combine the documents, the combination of Crooke, Hayden, and Ntambi does not

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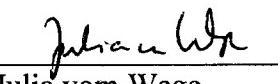
render obvious the claimed invention. Without the use of improper hindsight, one of skill in the art would not have understood from Crooke's or Hayden's disclosure to measure insulin sensitivity. It would not have been obvious to the skilled artisan to undertake the recited steps because the art at the time of filing appreciated no link between insulin sensitivity and SCD1 modulation, as Hayden became available only after the filing of the instant application.

Reconsideration is respectfully requested.

Fees

A Petition for an extension of time for three months accompanies this Response so the Response will be deemed to have been timely filed. Please charge the fee due to the Deposit Account 17-0055. No other fee is believed due in connection with this submission. If a fee is due, in this or any subsequent response, please charge the fee to the same Deposit Account.

Respectfully submitted,



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